



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-99

September 11, 2000

Santiago Aremcibia Jr., president
Gulf Seafood of Key West, Inc.
6001 Peninsula Avenue
Stock Island, FL 33040

Dear Mr. Aremcibia:

We inspected your firm, at the above address on August 22, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your scombroid fish and cooked stone crab claws to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for scombroid species of fish to control the food safety hazard of histamine formation. We also note that you have a HACCP plan for cooked stone crab claws to control the food safety hazard of pathogen survival, which lacks the hazard of pathogen growth and a critical control point at storage, and has not been implemented.

You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not consistently maintain sanitation control records on each day that you processed cooked stone crab claws.

We previously sent you an Untitled Letter dated February 2, 2000, which listed the failure of your HACCP plan for cooked stone crab claws to include a critical control point for storage and the failure to maintain sanitation control records for cooked stone crab claws. We do not have a record of any response to this letter. We did receive a response dated August 24, 2000 on your stationary to the FD-483 issued at the conclusion of the latest inspection. However, the

author of this letter is unknown to us and we find this response to be inadequate, as it does not mention any specific corrective action or provide any documentation of corrections already made. A copy of the Untitled Letter and August 24, 2000 response letter is attached for your reference.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, such as a HACCP plan for scombroid species of fish, a revised HACCP plan for stone crab claws and revised monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton for".

Emma R. Singleton,
Director, Florida District